510 (K) Summary

Revolution™ 45 MHz Rotational IVUS Imaging Catheter

Date Prepared: April 18, 2005

Submitted by: Volcano Corporation
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact person: Lorry W. Huffman
Director, Regulatory Affairs

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Device Name: Revolution™ 45 MHz Rotational IVUS Imaging Catheter

Classification name:	**Class**
• 870.1200 Diagnostic Intravascular catheter	II
• 892.1560 Ultrasonic pulsed echo imaging system	II
• 892.1570 Diagnostic ultrasonic transducer	II

Predicate Device:
The Revolution™ 45 MHz Rotational Imaging Catheter is substantially equivalent to the Scout 3.2/45 MHz Coronary Imaging Catheter cleared under K974457 on July 14, 1998.

Device Description:

Crossing profile at transducer	3.2F nominal
Length	135 cm nominal
Maximum pullback length	150 mm
Maximum Guide Wire O.D.	0.014" (0.36mm)
Minimum Guide Catheter	6F (1.63mm)

Materials supplied in sterile packaging:

- Revolution™ 45 MHz Rotational IVUS Imaging Catheter
- 10" extension tubing
- 3cc syringe
- 10cc syringe

- 3-way stopcock
- Sterile PIM bag

The Revolution™ 45 MHz Rotational IVUS Imaging Catheter consists of two main assemblies; the imaging core and the catheter body. The catheter body comprises three sections; the distal section with a 0.014" compatible F/X port, single lumen proximal section, and a telescope section. The distal section and proximal single lumen sections comprise the useable length of the catheter, the telescoping section remains outside of the guiding catheter. The telescope shaft allows the imaging core to be advanced and retracted for up to 150mm of linear movement. The corresponding movement of the transducer occurs from the proximal end of the guide wire exit port to the proximal end of the window portion of the distal section.

The imaging core is composed of a hi-torque, flexible, rotating drive cable with an outward looking 45MHz ultrasonic transducer at the distal tip. An electromechanical connector interface at the proximal end makes the connection to the patient-user interface (PIM) instrument. The PIM-catheter interface consists of an integrated mechanical drive assembly and electrical connection.

A flush port with a one-way valve is used to displace the air. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way valve helps retain saline in the catheter during use.

The catheter body has a distal guidewire lumen with proximal exit port at 2cm from the distal end. A coupling is used to attach the catheter body to the telescope shaft. A radiopaque (RO) marker is embedded in the catheter body at 0.5cm from the tip. In addition, two insertion depth indicators are located on the catheter body at 90cm corresponding to brachial insertions, and at 100cm corresponding to femoral insertions.

Intended Use:

The Revolution™ 45 MHz Rotational IVUS Imaging Catheter is intended for the intravascular ultrasound examination of coronary arteries. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Device Technological Characteristics and Comparison to Predicate Device:

The Revolution™ 45 MHz Rotational IVUS Imaging Catheter is substantially equivalent to: Hewlett Packard 3.2/45 MHZ CORONARY IMAGING CATHETER (Intravascular Ultrasound Imaging Catheter) cleared under K974457 on July 14, 1998. The Scout rotational catheter device developed by Hewlett Packard and cleared under 510(k) K974457 is modified in several physical design aspects (the mechanism for retracting and advancing the imaging core was upgraded) as well as a few material changes or additions. The fundamental scientific technology remains the same; rotational ultrasound catheter.

The Revolution™ 45 MHz Rotational Imaging Catheter uses the same fundamental scientific technologies and has the same intended use as that of the predicate device, Scout 3.2/45 MHz Coronary Imaging Catheter.

Performance Data:
Applicable testing was performed in accordance with Design Controls including a risk analysis addressing the impact of modifications to the device and components. The device was tested for biocompatibility according to ISO 10993-1 and the results met the predetermined acceptance criteria.

Conclusion:
Revolution™ 45 MHz Rotational Imaging Catheter has the same *Intended Use* and utilizes the same *fundamental scientific technology* as that of the predicate device, Scout 3.2/45 MHz Coronary Imaging Catheter cleared under K974457 on July 14, 1998. Modifications to the device do not raise any new questions regarding safety and efficacy. The performance data and a declaration of conformity with design controls support a determination of substantial equivalence of the modified device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2007

Volcano Corp.
c/o Ms. Lorry Huffman
Director, Regulatory Affairs
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K050995
Trade/Device Name: Revolution 45 MHz Rotational IVUS Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: II
Product Code: OBJ
Dated: April 18, 2005
Received: April 20, 2005

Dear Ms. Huffman:

This letter corrects our substantially equivalent letter of June 20, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

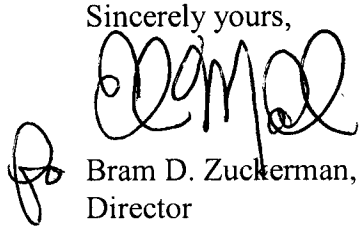
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-4008. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050995

Device Name: Revolution™ 45 MHz Rotational IVUS Imaging Catheter

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Prescription Use ____X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050995